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AB-165U

Serial No.: 10/057,116

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application: Todd K. Whitehurst et al.	**Confirmation No.:** 1864
Application No.: 10/057,116	**Examiner:** SCHAETZLE, Kennedy
Filed: January 24, 2002	**Group Art Unit:** 3766
Title: "Fully Implantable Neurostimulator for Peripheral Nerve Stimulation as a Therapy for Chronic Pain"	

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Sir:

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on October 9, 2006.

The fee for filing this Appeal Brief is (37 CFR 1.17(c)) $500.00.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provision of 37 CFR 1.136 (a) apply.

( ) (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: CFR 1.17(a)-(d)) for the total number of months checked below:

( )	one month	$60.00
( )	two months	$225.00
( )	three months	$510.00
( )	four months	$795.00

( ) The extension fee has already been filed in this application

(X) (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant had inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 18-0013/40328-0030 the sum of $500.00. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 18-0013 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 18-0013 under CFR 1.16 through 1.21 inclusive, and any other section in the Title 37 of the Code of Federal Regulations that may regulate fees. A duplicate copy of this sheet is enclosed.

(X) I hereby certify that this paper is being transmitted to the Patent and Trademark Office facsimile number (571) 273-8300 on December 8, 2006.

Number of pages: 34

Signature: Rebecca R. Schow

Respectfully submitted,

By:

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10/057,116

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent Application of

Todd K. Whitehurst et al.

Application No. 10/057,116

Filed: January 24, 2002

For: "Fully Implantable Neurostimulator for Peripheral Nerve Stimulation as a Therapy for Chronic Pain"

Group Art Unit: 3762

Examiner: SCHAETZLE, Kennedy

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
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Sir:

This is an Appeal Brief under Rule 41.37 appealing the final decision of the Primary Examiner dated July 14, 2006. Each of the topics required by Rule 41.37 is presented herewith and is labeled appropriately.

I. Real Party in Interest

The present application has been assigned by the inventors to Advanced Bionics Corporation of Valencia, California. Consequently, Advanced Bionics Corporation is the real party in interest on this appeal.

II. Related Appeals and Interferences

There are no appeals or interferences related to the present application of which the Appellant is aware.

III. Status of Claims

Claims 12-14 and 23-26 were withdrawn under a Restriction Requirement and cancelled previously without prejudice or disclaimer. During subsequent prosecution of the application claims 1-3, 7, 9-11, 17-19, 21, 22 and 28 were also cancelled without prejudice or disclaimer.

Therefore, claims 4-6, 8, 15, 16, 20 and 27 are currently pending in the application and all stand finally rejected. Appellant appeals from the final rejection of claims 4-6, 8, 15, 16, 20 and 27, which claims are presented in the following Appendix.

IV. Status of Amendments

Following the final Office Action of July 14, 2006, Appellant filed an after-final amendment under 37 C.F.R. § 1.116 on September 1, 2006. In that amendment, claim 27 was amended and rewritten into independent form. No other change was made to the substance of

claim 27. No other changes to the application were proposed by the amendment of September 1, 2006.

In an Advisory Action dated September 19, 2006, the Examiner indicated that the after-final amendment of September 1, 2006 would be entered on appeal. Consequently, the Claims Appendix attached below presents claim 27 in independent form as per the amendment of September 1, 2006.

Concurrent with the present brief, Appellant has filed another after-final amendment to correct a minor typographical error in claim 15. This amendment raises no new issues and has no substantive effect on any issue presented by this appeal. Appellant now awaits a decision by the Examiner on whether the after-final amendment filed with the present brief will be entered.

V. Summary of Claimed Subject Matter

Pain is recognized as a major public health problem. It is estimated that chronic pain affects 15% to 33% of the U.S. population, or as many as 70 million people. In fact, chronic pain disables more people than cancer or heart disease and costs the American people more than both combined. Pain costs an estimated $70 billion a year in medical costs, lost working days, and workers' compensation. (Appellant's specification, paragraph 0006).

The most common conditions associated with chronic neuropathic pain include: (1) Painful Peripheral Neuropathy (PN), including Diabetic Neuropathy (DN) and Traumatic Peripheral Nerve Injury; (2) Post-Herpetic Neuralgia (PHN); (3) Reflex Sympathetic Dystrophy/Complex Regional Pain Syndrome (RSD/CRPS); (4) Fibromyalgia Syndrome (FMS); (5) failed back surgery syndrome (FBSS); and (6) arachnoiditis. (Appellant's specification,

paragraphs 0007-13). Additional forms of chronic peripheral pain include, but are not limited to occipital neuralgia, peripheral pelvic pain, certain types of cardiac pain, and certain types of back pain. (Appellant's specification, paragraph 0014).

Appellant's specification describes means for chronically stimulating one or more peripheral nerves with a miniature implantable neurostimulator(s) that can be implanted with a minimal surgical procedure. To treat painful peripheral neuropathy and other forms of chronic pain, a miniature implantable neurostimulator, such as a Bionic Neuron (also referred to as a BION® microstimulator), may be implanted via a minimal surgical procedure (e.g., small incision) adjacent to one or more peripheral nerves. Nerves that may be stimulated by such a stimulator include, but are not limited to, one or more ulnar nerve, median nerve, radial nerve, common peroneal nerve, sciatic nerve, saphenous nerve, and intercostal nerves. A number of peripheral nerves, especially those in the extremities and in the thorax, lie relatively close to the surface of the skin and are surrounded by relatively few if any surgical barriers. A miniature neurostimulator may thus easily be implanted adjacent to a peripheral nerve. (Appellant's specification, paragraph 0015).

Turning to specific claims, claim 4 recites:

A method for treating a patient with chronic pain *(Appellant's specification, paragraph 0002)*, comprising:

identifying a patient experiencing sensations of chronic pain *(Appellant's specification, paragraph 0037)*;

providing at least one leadless stimulator (150) having at least two electrodes (156, 158) *(Appellant's specification, paragraph 0047)*;

implanting the at least one leadless stimulator (150) adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient *(Appellant's specification, paragraph 0015)*;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters *(Appellant's specification, paragraph 0054-55)*; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient *(Appellant's specification, paragraph 0054-55)*;

wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve *(Appellant's specification, paragraph 0015)*;

wherein the at least one peripheral nerve comprises at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve *(Appellant's specification, paragraph 0044)*.

Claim 8 recites:

A method for treating a patient with chronic pain *(Appellant's specification, paragraph 0002)*, comprising:

identifying a patient experiencing sensations of chronic pain *(Appellant's specification, paragraph 0037)*;

providing at least one leadless stimulator (150) having at least two electrodes (156, 158) *(Appellant's specification, paragraph 0047)*;

implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters *(Appellant's specification, paragraphs 0054-55)*; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient *(Appellant's specification, paragraphs 0054-55)*;

wherein the chronic pain is located in one or both lower limbs, and the at least one stimulator is implanted adjacent to at least one nerve fiber of a common peroneal nerve, a common peroneal nerve branch, a sciatic nerve, a sciatic nerve branch, a saphenous nerve, a saphenous nerve branch *(Appellant's specification, paragraph 0088)*, a posterior cutaneous nerve, a posterior cutaneous nerve branch, a sural nerve, a sural nerve branch, an obturator nerve, an obturator nerve branch, a femoral nerve, a femoral nerve branch, a lateral cutaneous nerve, and a lateral cutaneous nerve branch *(Appellant's specification, paragraph 0043)*.

Claim 15 recites:

A method for treating a patient with chronic pain *(Appellant's specification, paragraph 0002)*, comprising:

identifying a patient experiencing sensations of chronic peripheral pain *(Appellant's specification, paragraph 0037)*, wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome *(Appellant's specification, paragraph 0080)*, arachnoiditis *(Appellant's specification, paragraph 0013)*, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain *(Appellant's specification, paragraph 0014)*;

providing at least one leadless stimulator (150) having at least two electrodes (156, 158) *(Appellant's specification, paragraph 0047)*;

providing at least one sensor *(Appellant's specification, paragraph 0064)*;

implanting the at least one leadless stimulator (150) adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient *(Appellant's specification, paragraph 0015)*;

providing operating power to the at least one stimulator *(Appellant's specification, paragraph 0068)*;

using the sensor to sense a physical condition *(Appellant's specification, paragraph 0064)*;

determining stimulation parameters based upon the sensed condition *(Appellant's specification, paragraph 0064)*;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters *(Appellant's specification, paragraphs 0054-55)*; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient *(Appellant's specification, paragraphs 0054-55)*;

wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve of the patient *(Appellant's specification, paragraph 0015)*.

Claim 27 recites:

A method for treating a patient with chronic pain *(Appellant's specification, paragraph 0002)*, comprising:

providing at least one leadless stimulator (150) having at least two electrodes (156, 158) *(Appellant's specification, paragraph 0047)*;

implanting the at least one leadless stimulator (150) adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for

the sensations of chronic pain experienced by the patient *(Appellant's specification, paragraph 0015)*;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters *(Appellant's specification, paragraphs 0054-55)*;

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient *(Appellant's specification, paragraphs 0054-55)*;

wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve *(Appellant's specification, paragraph 0015)*;

transmitting data from a transmitter of said stimulator to an external device *(Appellant's specification, paragraph 0071)*; and

transmitting said stimulation parameters to said external device *(Appellant's specification, paragraph 0071)*.

VI. Grounds of Rejection to be Reviewed on Appeal

In the final Office Action of July 14, 2006, the following grounds of rejection were made against the present application.

(1) Claims 1-11 and 15-22 were rejected as unpatentable under 35 U.S.C. § 103(a) over the combined teachings of WO 98/37926 to Schulman et al. ("Schulman") and an article entitled "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain," by Novak et al. ("Novak"). Appellant notes that this rejection has been rendered moot except as to claims 4-6, 8, 15, 16 and 20.

(2) Claims 27 and 28 were rejected as being unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Schulman, Novak and U.S. Patent No. 6,480,745 to Nelson et al. ("Nelson"). Appellant notes that this rejection has been rendered moot except as to claim 27.

Therefore, Appellant respectfully requests review of both these grounds of rejection as they apply to the remaining claims in the present appeal.

VII. Argument

Claim 4:

Claim 4 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic pain;
> providing at least one leadless stimulator having at least two electrodes;
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
> generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and
> delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
> wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;
> *wherein the at least one peripheral nerve comprises at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.*

(emphasis added).

In contrast, the cited combination of prior art references fails to teach or suggest a method of treating a patient with chronic pain including delivering stimulation pulses with a leadless stimulator to *"at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve."* The final Office Action

implicitly concedes that this is the case. The Action is unable to cite to any portion of the prior art that actually teaches or suggests the claimed method including delivering stimulation pulses to the specific target nerves listed.

Rather, the final Office Action addresses claim 4 as follows. "[B]ecause Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation." (Action of 7/14/06, p. 3). Appellant notes that claim 4 does not merely recite implanting a device near any peripheral nerve. In this regard, the final Action fails to actually address the specific recitations of claim 4.

Claim 4 actually recites a method of treating a patient with chronic pain including delivering stimulation pulses with a leadless stimulator to at least one of "*an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.*" The final Office Action fails to address these specific nerve sites and fails to argue how and where the prior art teaches delivering stimulation pulses at these specific nerve sites to treat chronic pain.

Rather, the Action appears to take the position that because the prior art teaches stimulating certain nerves to treat non-chronic pain, it would be obvious to stimulate any other nerve site to treat chronic pain. (Action of 7/14/06, p. 5). This is clearly reading far too much into the prior art. One of ordinary skill in the art, e.g., a physician, would never make such a leap in reasoning.

The teachings of the prior art can be extended, as Applicant has done. However, such extension requires careful experimentation and discovery, i.e., patentable invention. This is what Applicant has achieved.

Referring again to the Office Action, the Action argues that "it would have been obvious to implant the device near a peripheral nerve *if the peripheral nerve required stimulation.*" (Action of 7/14/06, p. 3) (emphasis added). This statement illustrates the leap in reasoning being made by the Action. How does one determine "if the peripheral nerve require[s] stimulation?" The Action fails to answer this question.

Rather, according to the Action, the "type of pain to be treated and the physiology of the nervous system would naturally dictate where the most effective application site resides." (Action of 7/14, 06, p. 3). If this is an allegation that one of skill in the art would, based on prior art teachings, obviously modify the teachings of Schulman and Novak to deliver stimulation pulses at the nerve sites claimed by Applicant, Applicant respectfully requests that prior art be cited to support this conclusion. Applicant notes that "[t]he examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being "well-known" in the art. *In re Ahlert*, 424 F. 2d 1088, 165 USPQ 418, 420 (CCPA 1970). . . . [However, if] the applicant traverses such an assertion the examiner should cite a reference in support of his or her position." M.P.E.P § 2144.03.

The bottom line is that the cited prior art does not teach or suggest the claimed method of treating a patient with chronic pain by delivering stimulation pulses with a leadless stimulator implanted adjacent to at least one of "an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve." The final Action fails to indicate how or where the prior art teaches delivering the claimed stimulation pulses to the specific nerve sites claimed via a device implantable adjacent these nerves.

MPEP 2131 further states: "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The final Office Action has failed to meet this standard.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). Schulman does not teach or suggest a method of stimulating nerves that include any of the nerves now recited in claim 4. Novak likewise does not teach or suggest a method including stimulation of any of the nerves now recited in claim 4. Consequently, the applied prior art, taken alone or in combination, does not teach or suggest the method of claim 4.

It is incumbent upon the Office to cite prior art that actually teaches the subject matter of Applicant's claims. M.P.E.P. § 706.02(j). In the present case, the prior art of record does not teach or suggest the method of claim 4 including the specific stimulation sites recited for the purpose of treating chronic pain. For at least these reasons, the rejection of claim 4 should not be sustained.

Claim 8:

Claim 8 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic pain;
> providing at least one leadless stimulator having at least two electrodes;
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the chronic pain is located in one or both lower limbs, and the at least one stimulator is implanted adjacent to at least one nerve fiber of a common peroneal nerve, a common peroneal nerve branch, a sciatic nerve, a sciatic nerve branch, a saphenous nerve, a saphenous nerve branch, a posterior cutaneous nerve, a posterior cutaneous nerve branch, a sural nerve, a sural nerve branch, an obturator nerve, an obturator nerve branch, a femoral nerve, a femoral nerve branch, a lateral cutaneous nerve, and a lateral cutaneous nerve branch.

(emphasis added).

The final Office Action does not address the details or specific recitations of claim 8. Rather, the final Action merely states that "all of the above comments made in support of the rejection of similarly worded limitations apply here as well." (Action of 7/14/06, p. 4). However, there has been no other claim in this application that also recites the subject matter emphasized above in claim 8. Rather, as with other claims in this application, the Office Action chooses to simply overlook some of the features recited.

Claim 8 recites a method of treating chronic pain located in one or both lower limbs with an implanted stimulator that is implanted adjacent to and stimulates at least one of a list of specific nerve sites. In contrast, neither Schulman nor Novak teach or suggest a method including implantation adjacent to and stimulation of any of the listed nerves to treat chronic pain. The final Office Action fails to address these particular nerve sites or to explain how or why it would be obvious from the prior art to implant a leadless stimulator adjacent at least one nerve fiber of these particular nerves to stimulate these sites to treat chronic pain as in the method of claim 8.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 8 should not be sustained.

Claim 15:

Independent claim 15 recites:

> A method for treating a patient with chronic pain, comprising:
> identifying a patient experiencing sensations of chronic peripheral pain, *wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain*;
> providing at least one leadless stimulator having at least two electrodes;
> providing at least one sensor;
> implanting the at least one stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensation of chronic peripheral pain experienced by the patient;
> providing operating power to the at least one stimulator;
> using the sensor to sense a physical condition;
> determining stimulation parameters based upon the sensed condition;
> generating stimulation pulses within the at least one stimulator in accordance with the stimulation parameters; and
> delivering the stimulation pulses from the electrodes of the at least one stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
> wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve of the patient.

(emphasis added).

In contrast, neither Schulman nor Novak teach or suggest the claimed method for treating chronic pain, which includes "at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain." These maladies are not even mentioned by Schulman or Novak. Nor would it have been

obvious to one of skill in the art to take the teachings of Schulman and Novak and apply them to an entirely different group of patient conditions treated by stimulation at entirely different nerve locations. This subject matter simply is not taught or suggested by Schulman and Novak and clearly represents a patentable advance over those teachings.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 15 and its dependent claims should not be sustained.

Claim 27:

Claim 27 recites:

> A method for treating a patient with chronic pain, comprising:
> providing at least one leadless stimulator having at least two electrodes;
> implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
> generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters;
> delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient; wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;
> transmitting data from a transmitter of said stimulator to an external device; and
> *transmitting said stimulation parameters to said external device.*

(Emphasis added).

In contrast, the cited combination of prior art fails to teach or suggest a method in which an implanted stimulator transmits its stimulation parameters to an external device. In this regard,

the final Office Action refers to Nelson at col. 2, lines 39-67. (Action of 7/14/06, p. 4). This portion of Nelson reads as follows:

> After the implantation of an IMD [Implantable Medical Device], for example, a cardiac pacemaker, clinician involvement with respect to the IMD has typically only begun. The IMD usually cannot be merely implanted and forgotten, but must be monitored for optimal results, and may require occasional adjustment of certain parameters or settings, or even replacement, in response to or in anticipation of changes in patient condition or other environmental factors, or based on factors internal to the device. IMDs may also contain logic devices such as digital controllers, which may need to undergo firmware or software upgrades or modifications. In addition, information about the IMD may be gathered for treatment or research purposes. For example, many IMDs are capable of storing certain state information or other data regarding their operation internally in addition to physiological data.
>
> Because IMD operation and patient physiology is preferably monitored to help effect the desired patient outcome, it would be desirable if data collected by an IMD could be viewed remotely. Similarly, it would also be desirable that the instructions installed in an IMD may be modified in response to patient physiologic information, or perhaps be upgraded remotely as well.
>
> In the event a change, modification or reprogramming of the IMDs is indicated, it would be desireable [sic] if the instruction could be implemented in the IMD as soon as possible, thus providing more continuous monitoring to proactively effect changes in the IMDs for efficient therapy and clinical care. This scenario may be contrasted with existing practice of responding to an adverse patient event or subjecting the patient to the inconvenience or expense of frequent in-person encounters with a clinician, for example after an unexpected therapy by the device, or to effect other monitoring of device functioning, e.g., spontaneous therapies by the device. For example, an implanted cardioverter defibrillator may administer to the host patient a cardioversion or defibrillation therapy. After such therapy, it is typically desirable to determine the parameters of, for example, an arrhythmia that a therapy was administered in response to, or of the therapy administered.

(Nelson, col. 2, lines 39-67).

This portion of Nelson does not teach or suggest that the implanted device transmits its own stimulation parameters to an external device as recited in claim 27. To the contrary, Nelson appears only to teach that "patient physiologic data detected by a deployed IMD 112 will be transmitted via IMDNI 116 to computer 220 for purposes of analysis of this data." (Nelson, col.

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11, lines 13-15). This patient physiologic data may be used to determine a change to treatment regimens and/or IMD instructions, firmware, or software. (Nelson, col. 11, lines 16-18). However, Nelson does not ever teach or suggest that stimulation parameters are transmitted by the implant to an external device as recited in claim 27.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 27 should not be sustained.

In view of the foregoing, it is submitted that the final rejection of the pending claims is improper and should not be sustained. Therefore, a reversal of the Final Rejection of July 14, 2006 is respectfully requested.

Respectfully submitted,

DATE: December 8, 2006

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Rebecca R. Schow

VIII. CLAIMS APPENDIX

1-3. (cancelled)

4. (previously presented)A method for treating a patient with chronic pain, comprising:

identifying a patient experiencing sensations of chronic pain;

providing at least one leadless stimulator having at least two electrodes;

implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;

wherein the at least one peripheral nerve comprises at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.

5. (original) The method of Claim 4 wherein the stimulation pulses are delivered at less than about 1-10 mA.

6. (previously presented) The method of Claim 4 wherein the stimulation pulses are delivered at less than about 100 to 150 Hz.

7. (cancelled)

8. (previously presented) A method for treating a patient with chronic pain, comprising:

identifying a patient experiencing sensations of chronic pain;

providing at least one leadless stimulator having at least two electrodes;

implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the chronic pain is located in one or both lower limbs, and the at least one stimulator is implanted adjacent to at least one nerve fiber of a common peroneal nerve, a

common peroneal nerve branch, a sciatic nerve, a sciatic nerve branch, a saphenous nerve, a saphenous nerve branch, a posterior cutaneous nerve, a posterior cutaneous nerve branch, a sural nerve, a sural nerve branch, an obturator nerve, an obturator nerve branch, a femoral nerve, a femoral nerve branch, a lateral cutaneous nerve, and a lateral cutaneous nerve branch.

9-14. (cancelled)

15. (previously presented) A method for treating a patient with chronic pain, comprising:

identifying a patient experiencing sensations of chronic peripheral pain, wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripherial pelvic pain, cardiac pain and back pain;

providing at least one leadless stimulator having at least two electrodes;

providing at least one sensor;

implanting the at least one stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensation of chronic peripheral pain experienced by the patient;

providing operating power to the at least one stimulator;

using the sensor to sense a physical condition;

determining stimulation parameters based upon the sensed condition;

generating stimulation pulses within the at least one stimulator in accordance with the stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve of the patient.

16. (original) The method of Claim 15 wherein the at least one sensor is a part of the stimulator.

17-19. (cancelled)

20. (original) The method of Claim 15 further comprising providing and implanting more than one stimulator.

21-26. (cancelled)

27. (previously presented) A method for treating a patient with chronic pain, comprising:

providing at least one leadless stimulator having at least two electrodes;

implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters;

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient; wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;

transmitting data from a transmitter of said stimulator to an external device; and

transmitting said stimulation parameters to said external device.

28. (cancelled)

IX. Evidence Appendix

None

X. Related Proceedings Appendix

None

XI. Certificate of Service

None